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No. 05-273

IN THE
SUPREME COURT OF THE UNITED STATES

FEDERAL TRADE COMMISSION,

Petitioner,

v.

SCHERING-PLOUGH CORPORATION, *et al.*

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

BRIEF OF AARP AND THE PRESCRIPTION ACCESS LITIGATION PROJECT AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

INTEREST OF *AMICI CURIAE*[1]

The statements of interest are contained within the forgoing motion for leave to file this brief.

[1] Pursuant to Supreme Court Rule 37.6, no counsel for any party authored any portion of this brief. No persons other than *amici curiae*, their members, or their counsel have made a monetary contribution to the preparation and submission of this brief.

SUMMARY OF ARGUMENT

The Eleventh Circuit expressly rested its decision on policy grounds but considered only the value of settlement of litigation, ignoring countervailing policies. Settlements of patent litigation, featuring reverse payments which delay entry of less expensive generic versions of drugs to market, frustrate Congressional attempts to allow generic entry when patents should not rightfully exclude competition. In the 1984 Hatch-Waxman Amendments, and now nearly 20 years later in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress has declared its policy to speed generic versions of drugs to market. Congress has acted because the high costs of prescription drugs are threatening consumers' health. Research shows that consumers react to higher prices by reducing consumption of drugs, but many will choose to switch to lower cost generic versions of drugs if they are available. The greatest price reductions result not from competition between a brand name and generic drug maker but from competition between generic drug makers as more of them enter the market. The Court should grant certiorari to determine if settlements of prescription drug patent disputes are beyond antitrust liability.

REASONS FOR GRANTING THE PETITION

A. Introduction.

While settlement of disputes may be a worthy policy goal, the Eleventh Circuit offers no reason why encouragement of prescription drug patent settlements should trump the countervailing considerations of fair market competition and consumer access to affordable medication. This Court should grant review because it should decide the important federal question the Eleventh Circuit identified, determining exactly

what is "the confluence of patent and antitrust law." *Schering-Plough v. FTC*, 402 F.3d 1056, 1076 (11th Cir. 2005). However, this Court should properly balance all the policy goals which Congress has sought to achieve, including those of competition and increasing consumers' access to lower cost prescription drugs.

B. Reverse Payments with Delay of Competition Patent Settlements May Be Win-Win for Drug Manufacturers But Are Lose-Lose For Competition and Consumers.

Schering, Upsher and AHP are not the only companies which have entered into settlements featuring reverse payments, in which, rather than resolving the patent dispute to determine whether the name brand manufacturer should have the ability to continue to exclude competition, the parties create a limbo where only consumers suffer harmful consequences. The name brand manufacturer wins because its patent remains unchallenged, and the generic manufacturer gets paid to not produce anything. The latter payments are known as reverse payments for two reasons. First, moneys paid in settlement normally flows to the injured party. Here, the alleged infringer gets the money, normally quite a handsome sum. Second, in patent disputes, where the patent's exclusion of competition is valid, payment normally flows to the pioneer in exchange for either infringement damages or a manufacturer's license. But in these settlements, money flows in the reverse direction, to the generic.

The FTC's 2002 study of whether settlements of prescription drug manufacturers' patent litigation often resulted in the practice of reverse payments found this perverse result surprisingly common. In that study, nine of twenty final patent litigation settlements contained provisions providing that the

brand-name manufacturer make a payment to the generic manufacturer. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, 17 (2002). Each of these agreements prohibited marketing of the generic until the patent expired or, in two cases, until an agreed-upon date. *Id.* at 31. The reverse payments ranged from $1.75 million to $132.5 million, and the delay of generic entry was from four months to ten years. *Id.*

C. Patent Settlement Agreements Amongst Manufacturers Which Delay Entry of Competition Pervert Congress' Intent to Speed Generic Entry.

1. Congress Intended To Benefit Consumers By Getting Generics to Market.

Twenty years ago Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act). Pub. L. No. 98-417, 98 Stat. 1585, *codified at* 35 U.S.C. § 271(e)(1) (2005). One of the major purposes of the legislation was "to make available more low cost generic drugs." H.R. Rep. No. 98-417, pt. 1, 2648-50 *reprinted in* 1984 U.S.C.C.A.N. 2647 (1984). Congress specifically noted its intent that "[o]lder Americans, in particular, would benefit" from the law because of their great need for affordable prescription drugs. *Id.* Government programs which paid for prescription drug coverage would also have substantial savings because of the availability of generic drugs. *Id.* at 2650.

Hatch-Waxman rewarded innovation by preserving patent holders' rights compromised by the time it took to secure

regulatory approval for the marketing of their medications, and, at the same time, created a regulatory process intended to prevent a *de facto* patent extension equal to the time it would take a competitor to comply with the regulatory requirements required to bring a drug or medical device to market. *See* H.R. Conf. Rep. No. 98-417, 2647-2648 (stating that a purpose of the bill is to make more generic drugs available and to increase incentives for new research and development). Hatch-Waxman intended to balance the rights of patent holders with the competing priority of speeding generic drugs to market.[2]

In order to create that balance, Congress altered the traditional relationship between pioneer and generic drug makers, including the assumed inviolability of patents, in order to speed generics to market. Hatch-Waxman did several things to weaken the monopoly powers granted to patented drug products. As this Court recently recognized in *Merck KgaA v. Integra Lifesciences I., Ltd.*, __ U.S. __, 125 S.Ct. 2372 *(2005)*, Congress created a statutory patent exception allowing the free use of patented items to perform experiments related to regulatory approval of health care products, prior to the expiration of the patent term. 35 U.S.C.§ 271(e)(1); *see also, Eli Lilly v. Medtronic*, 496 U.S. 661 (1990)(exception applies to medical devices).

Hatch-Waxman also created a mechanism to allow generic manufacturers to invent around and dispute a patent and then challenge that patent in court before bringing the generic to market. Congress established the abbreviated new drug application (ANDA), a shorter approval process for generic versions of drugs already on the market. 21 U.S.C.

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[2] *See* 97 Cong. Rec. 24,434 (1984) (statement of Cong. Waxman) (explaining that Congress "tried to balance . . . interests. That was the whole course of the negotiations on this legislation").

§ 355(j)(2)(a). The Act provides that the filing of an ANDA creates a constructive act of patent infringement. The generic can test the strength of the patent before the brand name incurs damage by the generic marketing its product, and the generic risks being liable to the brand for millions of dollars. 21 U.S.C. § 355(j)(5)(B) and (C). The first generic to file an ANDA which successfully demonstrates that it does not violate a patent is given a 180-day period of marketing exclusivity. 21 U.S.C. § 355(j)(5)(B)(iv) (1984), *amended by* 117 Stat. 2066, Pub. L. 108-173 § 1102 (2003). Congress intended this 180-day period to provide "a reward for challenging monopolists' abuse of weak patents[,]" and for bringing costly patent litigation against the patent-holder. James T. O'Reilly, *Prescription Pricing and Monopoly Extension: Elderly Drug Users Lose the Shell Game of Post-Patent Exclusivity*, 29 N. Ky. L. Rev. 413, 414 (2002).

Congress intended for courts to determine whether patents were sufficient to exclude competition. But these reverse payment settlement agreements which delay generic competition, not only block courts from rendering a decision as to the scope of the patent, but also deprive consumers of the very benefit the law sought to obtain: increased competition. Congressional purpose will be frustrated if the courts see these settlements as a natural by-product of Hatch-Waxman, rather than examine them for anti-competitive consequences to consumers. [3] The problem with settlements with reverse

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[3] *Compare In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 262 F. Supp. 2d 188, 252 (E.D.N.Y. 2003) (finding that reverse payments are a natural by-product of the Hatch-Waxman Act, "even if such payments were not contemplated or intended") *with* FTC Opinion at 28 (rejecting argument that reverse payments are a natural by-product of Hatch-Waxman based on Congressional intent).

payments is that they satisfy only one of the aspirations of Hatch-Waxman—the protection of the patent-holder, but do so by sacrificing the other aspiration of making generic drugs available sooner. Representative Waxman commented on this perversion, saying, "'The law has been turned on its head. . . . We were trying to encourage more generics and through different business arrangements, the reverse has happened.'"[4] The Act was intended to benefit consumers, not to allow a different allocation of the total profits on a drug between horizontal market participants.[5] Because these agreements block increased competition, the FTC is right to question them as unreasonable restraints on trade.[6]

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[4] Sheryl Gay Stolberg and Jeff Gerth, *Medicine Merchants Holding Down the Competition: How Companies Stall Generics and Keep Themselves Healthy*, N.Y. Times, July 22, 2000, *available at* www.dimenet.com/dpolicy/cgi/getlink.cgi?344 (quoting Cong. Waxman).

[5] *See* 97 Cong. Rec. 24,427 (1984) (statement of Cong. Waxman) (elaborating on the intent behind the Hatch-Waxman Act by observing that "at some point public policy calls for the free market system competition which will bring about the result of a lower price for the consumer. That is the purpose of this legislation").

[6] The Eleventh Circuit's categorization and rejection of the FTC's rule of law in this case as "automatically invalidating any agreement" with reverse payment and delay of generic entry seems utterly misplaced. *Schering*, at 1076. After a trial and appeal using the rule of reason analysis, this examination by the FTC of these companies' behavior can not appropriately be called an automatic invalidation.

2. Policy-Makers and Courts Must Monitor Manufacturers Who Game the System.

Congress has recognized that abusive practices of pioneer drug companies and potential generic competitors have stalled the arrival of generics on the market.[7] They are aware these tactics delay consumers' access to affordable medications. As a result, Congress recently amended the law and passed Title XI - "Access to Affordable Pharmaceuticals" of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), 117 Stat. 2066, Pub. L. 108-173 (codified in scattered sections of 21 U.S.C. and 42 U.S.C.). Congress limited the stay of generic competition granted to name brand manufacturers following instigation of litigation when generic manufacturers filed ANDAs to a single 30 month period, thereby "allowing lower-priced generic products to enter the market more quickly." Joint Explanatory Text to the MMA Conference Agreement, H.R. Conf. Rep. No. 108-391, at 836 (2003) *reprinted in* 2004 U.S.C.C.A.N. 2187. This prohibited the practice of name brand manufacturers from stacking patents to block competition for successive 30 month periods. Congress also restructured the 180-day exclusivity period to prevent "parking" of the exclusivity period through

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[7] *See* Testimony of Timothy J. Muris, Chairman Federal Trade Commission, before the United States Senate Committee on the Judiciary, *The FTC Study on Barriers to Entry in the Pharmaceutical Marketplace* (June 17, 2003) (presenting the findings of its report, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002)); David Gross, AARP Public Policy Institute, *Generic Drugs*, AARP Issue Brief at 15 (2003), *available at* http://research.aarp.org/health/ib61_generic.html.

pioneer-generic agreements not to market the generic, thereby delaying other generics indefinitely.

The law now provides that exclusivity is forfeited if the generic does not come to market within a set amount of time. 21 U.S.C. § 355 (j)(5)(D)(2005). Congress also required that notice of settlements like the ones in this case be filed with the government's antitrust agencies. *See* MMA, §§ 1111-1118 (codified at 21 U.S.C. § 355 (notes)). But unless the courts enforce the antitrust laws against parties whose settlement agreements delay or halt competition, the companies will continue to find ways to game the system benefitting themselves to the detriment of consumers.

D. Delaying Entry of Lower-Priced Generic Prescription Drugs Harms Consumers.

1. High Prescription Drug Costs Threaten Older Consumers' Health.

U.S. spending for prescription drugs has quadrupled since 1990, leaping from $40.3 billion to $179.2 billion in 2003.[8] Although prescription drug spending constitutes 11% of the total health care spending for the general population, it is one of the fastest growing components, increasing at double digit rates each of the last seven years. Kaiser Family Foundation, *Prescription Drug Trends* (Fact Sheet) 1 (May 2003), *available at* www.kff.org/rxdrugs/3057-03-index.cfm. Spending for prescription drugs grew by 10.7.% from 2002 to

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[8] Centers for Medicare & Medicaid Services, National Health Expenditures Aggregate Amounts and Average Percentage Change, by Type of Expenditure: Select Calendar Years 1980-2003 *at* www.cms.hhs.gov/statistics/nhe/historical/t2.asp.

2003, and outpaced growth in all other health care services.[9] Increased demand by an aging population, as well as new, more expensive drug therapies becoming available have contributed to rising drug spending. However, increased drug prices are a substantial contributor to the increase in our nation's expenditure on drugs. The increase in prices constitutes a quarter to one-third of the rise in drug spending. *See, e.g.*, David Kreling et al., *Prescription Drug Chartbook: An Update* 40 (Kaiser Family Foundation, 2001); Stanley S. Wallack et al., *Recent Trends in Prescription Drug Spending for Insured Individuals Under 65 and Age 65 and Older* (Schneider Institute for Health Policy, Brandeis University, 2001).

For older Americans, prescriptions account for 19% of the average total out-of-pocket spending on health care (not including home care and long-term nursing home costs). Prescription drugs comprise the largest category of their health care expenses after premium payments.[10] From 2000 to 2003, the average annual growth rate in manufacturers' prices of brand name drugs most used by older persons was 6%. David Gross, Stephen Schondelmayer, Susan Kaetzman, *Trends in Manufacturers Prices of Brand Name Prescription Drugs Used by Older Americans 2000 Through 2003*, #2004-06 AARP

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[9] *Id.*

[10] Normandy Brangan & Mary Jo Gibson, *FYI: The Cost of Prescription Drugs: Who Needs Help?*, AARP Public Policy Institute (Oct. 2000), *available at* http://research.aarp.org/health/fyi_cost .html. By 2014, prescription drug spending is expected to be $521.3 billion. Centers for Medicare & Medicaid Services, National Health Expenditures Amounts and Average Percentage Change by Type of Expenditure: Select Calendar Years 1998-2014 *at* www.cms.hhs.gov/statistics/nhe/projections-2004/proj 2004.pdf.

Public Policy Institute vi (May 2004 revised June 2004), *available at* http://research.aarp.org/health/2004_06_drugprices.pdf. This increase is much larger than the increase in inflation, and the gap between rising prescription drug prices and the general rate of inflation has been widening. On average, the manufacturer prices for widely used brand name prescription drugs rose 4.1% in 2000 and accelerated to 6.9% in 2002, while the annual rate of general inflation actually fell from 3.4% in 2000 to 2.3% in 2003. *Id.*

Research and surveys show that uninsured, older and chronically ill people go without drugs when costs become too great a factor. Jan Blustein, *Drug Coverage and Drug Purchases By Medicare Beneficiaries with Hypertension,* 19 Health Aff. 219, 228 (2000). This study of drug coverage analyzed the relationship between cost and purchases from a national sample of people 65 and older, finding that a "one-dollar increase in the out-of-pocket per tablet cost resulted in the purchase of 114 fewer tablets per year." *Id.* There is "specific, empirical evidence that financial barriers compel older Americans to forgo needed drug treatment." *Id.* A more recent survey confirmed those findings. Dana Gelb Safran, et al., *Prescription Drug Coverage and Seniors: Findings From A 2003 Survey* Health Aff. (Web Exclusive) 157-58 (Apr. 19, 2004) (12.8% of all adults report not getting prescription drugs because of cost.) A national survey of Americans aged 45 or older reported that more than one in five (22%) did not fill at least one prescription prescribed by their doctor. AARP, *Prescription Drug Use Among Persons Age 45+: A Chart Book June 2002,* 24 (2002), *available at* http://research.aarp.org/il/rx_charts.pdf. The cost of the drug was the main reason people cited for not getting their prescription filled. *Id.* at 25. Of particular concern is the fact that cost deters a growing proportion of the population from

taking medically necessary medicines, up from 13% during a 1986 survey to 22% in 2002. *Id.* at 72.

Without doubt, increasing access to lower-cost generic drugs is one way to assure that consumers will fill the prescriptions they are given and take the dosages they need. Each patent settlement agreement that results in generic competition being stifled or delayed means that individual consumers are going without because they cannot afford the monopolist's prices.

2. Generic Drugs Reduce Medication Costs and Consumers Quickly Substitute Generic Drugs, Causing a Decline in the Market Share of Brand Name Drugs As More Generics Enter the Market.

Because generic drugs are priced much lower than their brand name counterparts, they are a source of substantial savings. In 2003, the Food and Drug Administration reported that the average price of a brand name drug is $72 while the average price of its generic version is $17, or less than a quarter of the brand's price.[11]

Most of the reduction in total spending for a branded drug is caused by substitution of generic prescriptions for brand

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[11] U.S. Food and Drug Administration, *FDA White Paper: New FDA Initiative on Improving Access to Generic Drugs* (June 12, 2003), *available at* http://www.fda.gov/oc/initiatives/generics/whitepaper.html.

prescriptions.[12] Since consumers are likely to substitute a generic for a brand name, the name brand manufacturer has a strong incentive to limit the number of generic competitors in an effort to keep a greater market share.

The sooner more companies offer the same generic product, the greater the price competition and the lower price consumers pay for a generic version of a drug product.[13] At the time of market entry, the generic price is about 60% of the branded counterpart's price; within the first two years on the market, the generic price will decline by an average of 35%. Grabowski, *supra*, at n.13. As a result, after two years, the generic drug price falls to about one-third of the branded counterpart's price.

Highly successful blockbuster drugs face steeper declines in market share after generic entry than less successful

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[12] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* ch. 3 (July 1998), *available at* http://www.cbo.gov/showdoc.cfm?index=655&sequence =0. (hereinafter CBO); Henry Grabowski and John Vernon, *Longer Patents for Increased Generic Competition in the US: The Waxman-Hatch Act After One Decade*, 10 PharmacoEconomics 110, 115 (1996) (hereinafter Grabowski); Michie I. Hunt, BlueCross BlueShield Association, *Prescription Drug Costs: Federal Regulation of the Industry* 61 (2000).

[13] Bureau of Competition & Policy Planning, Federal Trade Commission, *In the Matter of 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications* 4-5 (Nov. 4, 1999) *available at* http://www.ftc.gov/be/v990016.htm; CBO, *supra* at ch. 3; Grabowski, *supra*, at 115; *see also In re Cardizem CD*, 332 F.3d 896 (6th Cir. 2003), *cert denied sub nom. Andrx Pharms., Inc. v. Kroger Co.*, No. 03-779 (Oct. 12, 2004).

branded products. Schering-Plough's successful K-Dur product faced a very steep decline when competition began – they lost $200 million in sales in one year. Schering reported K-Dur sales of $216 million in 2001, but in 2002, sales plunged to $16 million because of generic competition.[14] Today consumers can purchase 100 tablets K-Dur 20 for $62.23, or purchase the generic version Klor-Con M20 for $43.99.[15]

An agreement between Schering-Plough and its would-be competitors in 1997 which stalled competition until 2001 in the case of Upsher-Smith, and until 2004 in the case of ESI-Lederle, meant that millions of dollars of profits were maintained for the manufacturers, at the expense of consumers. Therefore, in situations like the one before the Court, where multiple generic competitors prepared to enter the market, but delayed entry after being paid not to enter the market, consumers are unjustly denied the lower price that generics would bring to the market. *See generally*, David Reiffen and Michael R. Ward, *Generic Drug Industry Dynamics* 4 (2002) ("generic drug prices fall with the number of competitors.")

Perhaps Schering could have prevented the competition if it had prevailed in the patent litigation, but through business arrangements with its competitors, it managed to insulate the only means of testing that patent to determine whether it could maintain a legal monopoly. Finding these actions inconsistent

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[14] Schering Plough Press Release, Schering-Plough Reports Sales, Earnings for 2002 Fourth Quarter and Full Year, Jan 23, 2003, *available at* http://www.schering-plough.com/schering_plough /news/release.jsp?releaseID=373944 last visited Sept.27, 2005.

[15] *See* drugstore.com, at http://www.drugstore.com/pharmacy/ prices/drugprice.asp?ndc=00085078701&trx=1Z5006 last visited Sept.28, 2005.

with Congressional intent, and resulting in harm to consumers, the federal agency responsible for enforcing our federal competition laws found the facts compelling enough to bring it to trial and decided that the agreements were an unreasonable restraint of trade. The Eleventh Circuit said that in evaluating the antitrust implications of a patent dispute, the analysis must "evaluate the strength of the patent." *Schering* at 1076. But the Eleventh Circuit did not examine the validity of the patent or whether the generic drugs did in fact infringe, but instead, presumed the patent was valid. *Schering*, at 1068. Based upon this, it concluded that the "exclusionary effects of the agreement" fell "within the protections of the '743 patent, and were therefore not illegal." *Schering*, at 1076. Discounting the Commission's evidentiary conclusions, the Eleventh Circuit substituted its judgment for whether or not the agreements were anti-competitive because it presumed the patent absolved the parties of antitrust liability.

V. CONCLUSION

The amount of competition between drug manufacturers directly impacts the costs people pay for medications, and the cost of medication has a direct correlation with whether or not people can afford to purchase and get the benefit of these drugs. Any delay in the availability of generic prescription drugs means that consumers' access to life-saving and health enhancing medications is being diminished. *Amici* believe the Eleventh Circuit's decision was flawed because it did not give sufficient weight to Congressional policy in Hatch-Waxman promoting generic competition even in the face of a patent.

For the foregoing reasons, this Court should grant certiorari and review the Eleventh Circuit's decision in this case to determine whether these agreements violated antitrust law.

September 30, 2005

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FEDERAL TRADE COMMISSION,

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Respondents.

On Writ of Certiorari to the United States Court of Appeals For the Eleventh Circuit

MOTION TO FILE *AMICUS CURIAE* BRIEF AND BRIEF OF BAYER CORPORATION AS *AMICUS CURIAE* IN OPPOSITION TO CERTIORARI

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MOTION TO FILE *AMICUS CURIAE* BRIEF OF BAYER CORPORATION IN OPPOSITION TO CERTIORARI

Bayer Corporation ("Bayer") respectfully moves for leave to file the attached amicus curiae brief, pursuant to Supreme Court Rule 37.2(b), in opposition to certiorari.

Bayer is a research and science driven company that is engaged in the research and manufacture of several different kinds of products, including pharmaceutical products.

The questions presented in the Petition significantly affect Bayer Corporation because it manufactures a variety of patented products including patented drugs, is involved in litigation with respect to those products, and has entered and may enter in the future into settlements of such litigation. Bayer Corporation is a co-defendant in an antitrust case arising from the settlement of patent litigation in which the district court recently granted summary judgment for defendants. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 523 (E.D.N.Y. 2005), *appeal filed*, No. 05-2851 (2d Cir.).

In accordance with Supreme Court Rule 37.2, Bayer represents that it obtained written consent from counsel for the petitioner to file amicus brief. Counsel for respondents Schering-Plough Corporation and Upsher-Smith Corporation declined to consent, however, thereby necessitating this motion. Sup. Ct. R. 37.2(b).

For these reasons and those set out in the accompanying brief, Bayer hereby moves the Court to allow it to appear as *Amicus Curiae*, and to submit its brief urging the Court to deny the petition for certiorari.

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STATEMENT OF INTEREST

The Statement of Interest of Bayer Corporation is included in the Motion to File.[1]

SUMMARY OF ARGUMENT

1. There is no circuit split or significant conflict as to the first question presented that warrants this Court's review. To the contrary, there now exists a significant body of uniform but still developing law holding both (i) that antitrust analysis of a pharmaceutical patent settlement must begin with an examination of the exclusionary effect of the patent and whether the settlement agreement exceeds that effect, and (ii) that payments from a patent holder to a potential infringer or challenger are not presumptively anticompetitive. The Petition fails to identify or address this growing body of case law, which contravenes the Commission's position here. Moreover, the Commission itself recently and correctly argued to this Court that there is no conflict in the circuits as to these issues.

2. Review is also unwarranted because the Petition asserts a theory of antitrust liability that was not the basis for the Commission's decision below and that has not been accepted by any circuit. The Commission's decision was based on the theory that the actual settlement chosen by the parties was unlawful because it prevented them from entering into a different settlement "better" for consumers. That position was rejected because it is contrary to the well-established rule that conduct does not run afoul of the antitrust laws solely because different conduct might yield greater competition.

The Petition now advances a different rationale, based on the proposition that patents confer only "probabilistic"

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[1] Pursuant to Supreme Court Rule 37.6, no person other than counsel identified on the cover participated in authoring this brief. No entities other than the *amicus* and counsel provided financial support for this brief.

rights, and that consumers have a property right in the possibility that a patent will be found invalid or not infringed. The Petition now contends that the settlement was therefore unlawful because it eliminated this "prospect" of competition. This new rationale does not merit review by this Court because it was not the basis of the Commission's decision and has not been accepted by any circuit. Because this theory would largely negate the value of patent rights and strongly deter most settlements of patent litigation, it should not be presented to this Court until further developed by the courts of appeals.

ARGUMENT

I. REVIEW OF THE EXCEPTIONALLY BROAD QUESTION PRESENTED IS NOT WARRANTED IN LIGHT OF THE ONGOING DEVELOPMENT OF THE LAW AND THE LACK OF ANY SPLIT IN THE CIRCUITS

The Petition primarily raises the broad question "[w]hether an agreement between a pharmaceutical patent holder and a would-be generic competitor, in which the patent holder makes a substantial payment to the challenger for the purpose of delaying the challenger's entry into the market, is an unreasonable restraint of trade." Pet. I. In mounting its attack on so-called "reverse payments" in patent settlements, the Petition criticizes as "startling" the conclusion of the court below that the antitrust analysis of a patent settlement must begin by examining the "exclusionary potential" of the patent and whether the agreements at issue had exceeded that potential. *Id.* at 11. Neither the Commission's surprise nor review of this question are warranted.

A. The Petition Ignores The Uniform Body Of Law Contrary To The Commission's Position Here

The Petition fails to acknowledge, much less to address, the significant and uniform body of law contrary to the two fundamental premises of the Commission's argument.

First, the courts have repeatedly held that antitrust analysis of a settlement agreement between a patent holder and a potential infringer must begin with an examination of the exclusionary effect of the patent and whether the agreement exceeded that effect. In reaching the same conclusion, Pet. App. 17a, the court below followed its prior ruling in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003), *cert. denied*, 125 S. Ct. 308 (2004), that, "[w]hen the exclusionary power of a patent is implicated . . . the antitrust analysis cannot ignore the scope of the patent exclusion." *Id.* at 1310. Thus, only those provisions of the agreements "found to have effects beyond the exclusionary effects of Abbott's patent may then be subject to traditional antitrust analysis." *Id.* at 1312.

This exclusionary effect analysis is wholly consistent with prior holdings by District of Columbia, Federal, Second, and Seventh Circuits.[2] Similarly, Judge Richard Posner, sitting as a district court judge, recently explained that conduct within the exclusionary effect of a patent could give rise to antitrust liability only where it is objectively baseless to assert that the patent is valid and infringed:

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[2] *See United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1128 (D.C. Cir. 1981) ("[T]he conduct at issue is illegal if it threatens competition in areas other than those protected by the patent, and is otherwise legal. . . . None of these restraints go beyond what the patent itself authorizes."); *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992) ("The appropriate criterion is whether Mallinckrodt's restriction . . . has ventured beyond the patent grant. . . . Should the restriction be found to be reasonably within the patent grant, *i.e.*, that it relates to subject matter within the scope of the patent claims, that ends the [antitrust] inquiry."); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981) ("[W]here a patent has been lawfully acquired, subsequent conduct permissible under the patent laws cannot trigger any liability under the antitrust laws."); *USM Corp. v. SPS Techs., Inc.*, 694 F.2d 505, 513 (7th Cir. 1982) (antitrust liability may lie "only upon proof of an anticompetitive effect beyond that implicit in grant of the patent").

> A firm that has received a patent from the patent office . . . and thus enjoys the presumption of validity that attaches to an issued patent, 35 U.S.C. § 282, is entitled to defend the patent's validity in court, to sue alleged infringers, and to settle with them whatever its private doubts, unless a neutral observer would reasonably think either that the patent was almost certain to be declared invalid, or the defendants were almost certain to be found not to have infringed it, if the suit went to judgment.

Asahi Glass Co. Ltd. v. Pentech Pharms., Inc., 289 F. Supp. 2d 986, 992-93 (N.D. Ill. 2003). Other District Courts agree that the exclusionary effect of the patent is the central inquiry of any antitrust analysis.[3]

Second, the courts have also consistently held that settlement payments from a patent holder to a potential generic manufacturer are *not* presumptively anticompetitive. Pet. App. 35a. The court below explained:

> We have said before, and we say it again, that the size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement remedy. Due to the asymmetrics of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a

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[3] *See, e.g., Ciprofloxacin*, 363 F. Supp. 2d at 523 ("The ultimate question — and this is the crux of the matter — is not whether Bayer and Barr had the power to adversely affect competition for ciprofloxacin as a whole, but whether any adverse effects on competition stemming from the Agreements were outside the exclusionary zone of the '444 Patent."); *In re Tamoxifen Citrate Antitrust Litig.*, 222 F. Supp. 2d 326, 331 (E.D.N.Y. 2002), *appeal pending*, No. 03-7641 (2d Cir.) (refusing to remand a suit challenging a Hatch-Waxman settlement because "plaintiffs cannot succeed on their claims without proving the invalidity or unenforceability of Zeneca's patent"). *But see In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517 (D.N.J. 2004). There, the court addressed the very same settlement by Schering-Plough that is the subject of the Petition here. In denying a motion to dismiss, the court followed the Commission's ruling that was reversed by the Eleventh Circuit in this case.

> potential infringer a substantial sum in settlement. . . . What we must focus on is the extent to which the exclusionary effects of the agreement fall within the scope of the patent's protection.

Id. at 34a-35a (internal citations omitted). That conclusion was fully consistent with its prior decision in *Valley Drug*, where the court explained that "[i]f Abbott had a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit. The failure to produce the competing terazosin drug, rather than the payment of money, is the [alleged] exclusionary effect . . . ." 344 F.3d at 1309.

Moreover, the Eleventh Circuit's rulings on this point are entirely consistent with numerous other recent decisions. As Judge Posner also explained:

> "Reverse payment" patent settlements . . . are criticized and sometimes invalidated on the theory that they prevent competition. Whether it is a sound theory may be doubted, since if settlement negotiations fell through and the patentee went on to win his suit, competition would be prevented to the same extent. A ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive.

Asahi Glass, 289 F. Supp. 2d at 994 (citations omitted); *see also Ciprofloxacin*, 363 F. Supp. 2d at 540 ("The test for determining the validity of the so-called reverse or exclusion or exit payment and the only question remaining is whether the Agreements constrained competition beyond the scope of the patent claims."); *Tamoxifen*, 222 F. Supp. 2d at 331-32 (rejecting plaintiffs' argument that "the Settlement